

# REFRACTORY CHRONIC MIGRAINE AND ONABOTULINUMTOXIN A: A CLINICAL SETTING EXPERIENCE

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## Objectives:

To assess OnabotulinumtoxinA (BoTNA) safety and efficacy as a prophylactic treatment for **refractory chronic migraine**

*defined as headache occurring at least 15 days per month with lack of responsiveness to at least two preventive medications with established efficacy, alone or in combination, given in appropriate doses over an adequate period of time (1)*

**Materials and methods:** From May 2015 to May 2016 we recruited patients meeting the clinical diagnostic criteria for both refractory chronic migraine and medication overuse. Patients were treated with BoTNA every three months, according to the standard procedure (155-195 units)(2). At baseline (T0) and after 6 months, before the third treatment (T1), a structured questionnaire was administered, including:

- a) *migraine features [frequency (headache days/month), pain severity (Verbal Numeric Scale, VNS), acute medicines consumption/month, disability (Headache Impact Test, HIT-6), ictal cutaneous allodynia (Allodynia Symptoms Check-list 12, ASC-12)];*
- b) *associated symptoms [fatigue (Fatigue Severity Scale, FSS), anxiety symptoms (Generalized Anxiety Disorder, GAD-7), depressive symptoms (Patient Health Questionnaire, PHQ-9)].*

Wilcoxon test was performed for the T0-T1 comparisons, results were expressed using median values (Me) and interquartile range (IQR).

**Results:** 31 patients were enrolled (M/F 7/24; age: Me=50.5 IQR=30); 1 patient discontinued the study after the first treatment due to eyelid ptosis. Thirty patients were evaluated at T1, changes in **migraine features** and **associated symptoms** are reported in Table 1 and 2.

We reported a statistically significant reduction in:

- a) **Frequency (P .000; r .50)**
- b) **Analgesic intake/month(P.000; r .51)**
- c) **FSS score (P .009; r .34)**

<b>Migraine features</b>	<b>T0</b>	<b>T1</b>
Frequency *	Me=30 IQR=14	Me=14 IQR=26
VNS	Me=8.25 IQR=5	Me=8 IQR=7
acute medicines consumption/month *	Me=20 IQR=30	Me=10 IQR=30
HIT-6	Me=65.5 IQR=24	Me=63 IQR=26
ASC-12	Me=7 IQR=13	Me=6 IQR=16

Table 1

<b>Associated symptoms</b>	<b>T0</b>	<b>T1</b>
FSS *	Me=47 IQR=54	Me=36 IQR=54
GAD-7	Me=10 IQR=18	Me=8 IQR=17
PHQ-9	Me=9 IQR=20	Me=7 IQR=19

Table 2

**Discussion:** BoTNA resulted well tolerated and effective in reducing frequency, acute medication use and migraine associated symptoms of daily living (fatigue) in refractory chronic migraineurs.

**Conclusion:** Despite the limitations of an open label study, these findings support the use of BoTNA not only in chronic migraine, but also in refractory chronic migraine even when most of other preventive medications failed.

## Bibliography:

1Martelletti P, Katsarava Z, Lampl C et al. Refractory chronic migraine: a consensus statement on clinical definition from the European Headache Federation. J Headache Pain. 2014;15:47.

2Aurora SK, Winner P, et al. OnabotulinumtoxinA for treatment of chronic migraine: pooled analyses of the 56-week PREEMPT clinical program. Headache 2011;51(9):1358-73